In re National Prescription Opiate Litigation: MDL No. 2804

GENERIC MANUFACTURERS'
MOTION FOR PARTIAL SUMMARY JUDGMENT
Summary Sheet of Concise Issues Raised

Motion Name: Generic Manufacturers' Motion For Partial Summary Judgment

Concise Description of Issue:

Issue: Should the Court grant partial summary judgment in favor of Generic Manufacturers as to all false marketing claims asserted against them by Plaintiffs Summit and Cuyahoga Counties?

Answer: Yes, for several reasons. First, Generic Manufacturers do not promote the safety or efficacy of any of their generic medicines. And if there is no promotion, there is no false promotion. Plaintiffs have no evidence to the contrary. Indeed, after extensive discovery, the undisputed facts confirm that Generic Manufacturers have never engaged in the type of promotion that forms the basis for Plaintiffs' claims. Nor have Plaintiffs identified a single false statement by any Generic Manufacturer to any prescriber about any generic opioid medicine, much less one that caused Plaintiffs harm. No such evidence exists.

Second, Plaintiffs cannot bring these false marketing claims based upon a failure-to-disclose theory because such claims are preempted as a matter of controlling Supreme Court and Sixth Circuit law. The hallmark of the Hatch-Waxman Amendments to the Food Drug and Cosmetics Act is a duty of sameness, prohibiting a generic manufacturer from changing the design of a generic medicine, altering its FDA-approved labeling, or issuing additional warnings. Applying this "sameness" requirement, the Supreme Court and the Sixth Circuit have held that state law claims requiring generic manufacturers to communicate information beyond their FDA-approved labels are preempted regardless of how they are framed. Consistent with this controlling precedent, this Court affirmed the report and recommendation in the *Blackfeet* and *Muscogee* cases, which held that failure-to-disclose claims against generic manufacturers are preempted.

Lastly, Plaintiffs cannot argue that Generic Manufacturers are liable because they sold generic medicines in a market purportedly created by alleged false marketing of brand-name medicines by others companies. At bottom, this is a theory that manufacturers should have stopped selling their FDA-approved medicines because of other companies' marketing practices. This theory would impose liability for complying with FDA rules and regulations and would improperly force Generic Manufacturers to cease federally-lawful conduct. The Supreme Court and the Sixth Circuit have expressly rejected this "stop-selling" theory as incompatible with preemption jurisprudence.